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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
New York District Office
850 Third Avenue
Brooklyn, New York 11232

Telephone: [718] 340-7000 [Ext 5053] Fax: [718]340-7011

June 26, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Peter M. Derrico, President
Novasonics, Inc.
Four Nursery Lane
Rye, New York 10580

Ref: 34-NYK-98

Dear Mr. Derrico:

During an inspection of your firm located in Rye, NY between March 17 through 24, 1998 our investigator determined that your firm manufactures Esophageal Stethoscopes and Esophageal/Rectal Temperature Probes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our Center for Devices and Radiological Health has determined that these devices have a new intended use. The new intended use is the change from esophageal to esophageal/rectal use. Therefore, these devices are adulterated within the meaning of Section 501(f)(1)(B) in that the devices with its new intended use are Class III devices under Section 513(f) of the Act and do not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).

They are also misbranded within the meaning of Section 502(o) in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by section 510(k) and Title 21, Code of Federal Regulations, (CFR), Part 807.81(a)(3)(ii).

The above-stated inspection also revealed that the aforementioned devices as well as the LifeSound Heart & Breath Sound Monitor are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage or installations are not in conformance with the Current Good Manufacturing Practice (GMP) as specified in Title 21, Code of Federal Regulations, (CFR), Part 820, Quality System Regulations, as follows:

1. Failure to have established procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR 820.22]

2. Failure to establish, maintain and document procedures to ensure that the Esophageal Stethoscopes and the Esophageal Temperature Probes are routinely inspected and that the specified requirements of each stage completed. [21 CFR 820.72(a) & 820.75(b)]

3. Failure to establish and maintain written procedures to control labeling activities to ensure that the labels for the Esophageal Stethoscopes and the Esophageal and Rectal Temperature probes are checked for accuracy and that the proper labels used in packaging. [21 CFR 820.120 & 820.186]

4. Failure to monitor the production processes of the Novasonics LifeSound Heart & Breath Sound Monitor to ensure that it conforms to its specifications. The deviations observed includes: [21 CFR 820.70(a)]
   a) Forty-five units were manufactured that were outside of the specified power output between July 17, 1997 and March 24, 1998.
   b) The finished product test record revealed that the battery alarm is activating when the voltage is between 7.4 - 7.8 volts and not the specified 5.3 - 5.5 volts.

5. Failure to ensure that all inspection, measuring and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results in that there is no data to show that the Novasonics LifeSound Heart & Breath Sound Monitor will be operational for approximately 15 minutes when either the low battery indicator alarms or the low battery indication light comes on. [21 CFR 820.729(a)]

6. Failure to have established procedures for the finished device acceptance of the Novasonics LifeSound Heart & Breath Monitor to ensure that each production run, lot, or batch meets acceptance criteria. Specifically the product testing for the transmitter and receiver system performance test does not specify the nature of this test nor what would qualify as an acceptable result for this test. [21 CFR 820.80(d)]

7. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints. [21 CFR 820.198].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no Premarket notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer.

Very truly yours,

Brenda J. Holman
District Director

Enclosure: FDA form 483